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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,921	12/04/2001	Keith D. Allen	R-714	7082
26619	7590	07/28/2004	EXAMINER	
DELTAGEN, INC. 1031 Bing Street San Carlos, CA 94070			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/005,921

**Applicant(s)**

ALLEN ET AL.

**Examiner**

Ram R. Shukla

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Shukla, whereas any inquiries relating to formal matters should be directed to Ms. Jacob, LIE. The phone numbers for Examiner Shukla and LIE Jacob are provided at the end of this office action.
2. Applicants' response filed 5/18/04 has been received and entered.
3. Claims 1-27 have been cancelled.
4. Claims 28-34 have been entered.

### ***Claim Rejections - 35 USC § 112***

5. Claims 28-34 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reasons of record set forth in the previous office action of 12/03/03.

Claims 38-34 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for reasons of record set forth in the previous office action of 12/03/03.

### ***Response to Arguments***

Applicant's arguments filed 5/18/04 have been fully considered but they are not persuasive. Applicants have argued:

Specifically, the Examiner's rejection for lack of utility is based on an alleged lack of a correlation between the phenotypes exhibited by the claimed transgenic mice and any disease or disorder. The Examiner has further asserted that the evidence of record has failed to provide a correlation between any CASH related disease or disorder and the phenotypes exhibited by the transgenic mouse. Applicants respectfully disagree. Applicants submit that such a correlation has been provided by the instant specification, and is well-established in the art. Regardless,

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Applicants further argue that such an assertion is not necessary to establish utility and patentability. Applicants' arguments are not persuasive because correlation of a CASH gene to pain and seizure is necessary since the transgenic mouse was produced by disrupting the gene. Applicants' further arguments that transgenic knockout mouse represent a valuable tool for determining functions of genes in various disorders or conditions, while this is not disputed, applicants have not provided any evidence as to how a mouse knockout mouse whose characteristics do not have any relationship to the functions of the disrupted gene or a condition associated with the gene could be used for studying the function of a gene in a disorder. As discussed in the previous office action (see page 5), the phenotype of pain varies even among mice of different genetic backgrounds. Applicants' arguments that Crabbe reference fails to establish that phenotypic differences between a knock out transgenic mouse and wild-type control mouse are not real are besides the point because applicants have to provide evidence that the phenotype of the claimed transgenic mouse is due to disruption of CASH gene. Non-specificity of pain phenotype and hot plate test raise doubt based on sound scientific reasoning and state of the art and applicants have not provided any evidence except for arguments. Therefore, there is no evidence in the prior art of record or in the specification that the CASH gene disrupted in the instant invention has a role in pain or seizure. Applicants argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). Therefore, the utility rejection is maintained for reasons of record.

6. The rejection of claims 8, 10 and 14-21 are moot in view of the cancellation of these claims.

7. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

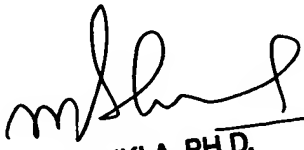
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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632

  
RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER